Statement on Importation of Prescription Drugs
Submitted by the
Academy of Managed Care Pharmacy
to the
United States Department of Health and Human Services
Task Force on Drug Importation
Friday, May 14, 2004

Mr. Chairman, and Members of the Task Force, the Academy of Managed Care Pharmacy appreciates the opportunity to participate as you receive testimony on issues relating to importation of prescription drugs. My name is Marv Shepherd, and I am the Director of the Center for Pharmacoeconomic Studies and Chairman of the Pharmacy Administration Division, College of Pharmacy, The University of Texas at Austin. I have been studying the issue of drug importation since 1994. I have written and made presentations on the subject extensively and have testified before congressional committees as an expert witness on this issue on numerous occasions.

The Academy of Managed Care Pharmacy (AMCP) is a professional association of pharmacists and associates who serve patients and the public by the promotion of wellness and rational drug therapy through the application of managed care principles. The Academy has more than 4,800 members nationally who provide comprehensive coverage and services to the more than 200 million Americans served by managed care. The foundation for the views presented in this statement is our member's responsibility as health care professional trained in medication therapy to serve the health care needs of patients.

The Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108-173 (MMA) gives the Secretary of Health and Human Services (HHS) the authority to implement a system in the United States for the importation of Canadian prescription drugs. However, Section 1121 of MMA permits the Secretary to implement this system only if he is first able to certify to the Congress that it would be safe and cost-effective. MMA contemplates two different methods of importation of prescription drugs that should be distinguished and evaluated separately by the Secretary in terms of their safety and cost effectiveness.

The first method of importation of prescription drugs is importation by individuals. AMCP is opposed to proposals that would allow individuals to import prescription drugs for personal use. There is no system for double checks on accuracy, no counseling, no one to call if questions arise. The potential for problems is particularly serious where U.S. citizens are ordering their prescriptions online. The prescription ordered via the internet from what is purportedly a Canadian pharmacy may in fact not be supplied by a Canadian pharmacy at all. It may never have been within the borders of Canada. Recent news stories have revealed that a company that helps Americans order medications from Canada is now using a British pharmacy to fill backordered prescriptions.[1] I am aware of

situations in which Americans believe they are receiving prescriptions dispensed in Canada when in reality these prescriptions are coming from a variety of sources. For example, a recent article in *Scrip* reports that one Canadian Internet Pharmacy Provider (Canadapharmacytrust.com) is shipping pharmaceuticals which were made in Mexico to U.S. residents. The article goes on to say that the drug products were not approved by Health Canada nor the FDA.[2]

Furthermore my research shows that in 2003 Canada imported pharmaceuticals from over 100 countries. Canada does have federally negotiated mutual recognition agreements with 18 Western European countries on Pharmaceutical GMPs (Good Manufacturing Processes). But as noted, Canada is importing drugs from over 100 countries including Ecuador, Mexico, Brazil, and China. From 2002 to 2003, Canadian imports from India have increase 109%, Singapore 72%, Mexico 50%, Italy 282%, plus many others. Even though U.S. pharmaceutical exports to Canada have increased nearly one billion dollars since 1999, as a proportion of all Canadian imports, U.S exports to Canada have been decreasing. In 2000, U.S. drugs comprised 55% of all Canadian drug imports, but in 2003 it has dropped to 43%. Canadian drug imports make up over half of the Canadian drug market.

The personal importation of pharmaceuticals in the U.S. is growing enormously and, in my opinion, is out of control. There is no guarantee that legislators, regulators and pharmacists can provide the information necessary to consumers letting them know whether the imported prescription drugs they are receiving are adulterated, counterfeit, or approved for use in the United States. There is no way for a consumer to determine whether their medication is safe to take, and there is no way for their local (U.S.) pharmacist to determine whether the medication is safe and effective.

Some manufacturers produce drugs to be sold outside the U.S. on a different manufacturing line than those marketed within the U.S. These drugs may have different formulations which may mean different salt forms and different bioavailability (which refers to how quickly the medication is absorbed into the body). One example is Synthroid, a widely used thyroid medication. The Synthroid made and sold in the U.S. is not the same Synthroid exported to Canada from the U.S. Switching patients who have been stabilized on one product to a product that is supposedly the same, but either made or sold in a foreign country, may create medical complications in some patients.

In addition, when patients receives their medications through individual importation, the community or mail-service pharmacists that review and provide safety checks on their prescription medications have no opportunity to intervene on the patient's behalf. No pharmacist is involved who can verify that the patient understands how to take the medication appropriately.

The second type of importation would allow the importation of certain prescription drugs by pharmacies and wholesalers. AMCP has concern with proposals that would allow the importation of prescription drugs for sale in the United States. AMCP understands that such proposals are being offered to address the plight of individuals unable to afford

much needed prescription drugs; eliminate unjustified global pricing disparities; and require members of the global economy to share reasonably in the costs of pharmaceutical research and development. As an organization representing health care professionals, AMCP believes that until it can be satisfactorily demonstrated that there are adequate resources to monitor the importation of prescription drugs in order to assure that their quality and safety have not been compromised, we will be unable to support these proposals.

By allowing pharmacies and drug distributors to purchase pharmaceuticals abroad for sale in the United States, importation proposals are intended to provide Americans access to prescription drugs at lower prices. AMCP supports the goal of lowering drug costs for the American consumer. However, the anticipated savings importation programs may generate is uncertain because of factors such as the differential in price for a specific drug in and out of the United States, the availability of the product for importation, and the additional overhead that may be needed for significant importing of drugs. For example, while Canadian drug prices for certain brand name products have been shown to be considerably less than prices in the United States, other drugs, particularly generics, are as reasonably priced in the United States as elsewhere. Foreign supplies of domestically produced drugs with dramatically lower prices may be inadequate to support large-scale importation thus limiting the potential savings available to American consumers through importation and creating shortages in the exporting country. We don't know - and we need to have more information and analysis to determine - if implementation of a drug importation program would actually result in savings to the American public and, if so, the likely extent of such savings

Importation also warrants study because it may pose unintended financial consequences for American consumers. AMCP believes that importation will result in decreased pharmaceutical innovation. Allowing the importation of pharmaceuticals may result in these negative effects and bring downstream cost-shifting by manufacturers to compensate for lost profits.

One of the potential unintended negative consequences of a program that permits pharmacies and wholesalers to import prescription drugs is a two-tiered system of drugs based on product cost. Because some states may base their reimbursement to pharmacies for dispensing prescriptions on an importation-based acquisition cost, it is not difficult to imagine that pharmacies would have to establish a dual inventory. For example, in a state with its own importation program, you could have state employees and those state residents eligible for a state pharmaceutical assistance program receiving imported drugs with the pharmacy reimbursed based upon the anticipated lower-priced imported drugs while those individuals who are covered under a private health plan would receive FDA-approved drugs with the pharmacy reimbursed based on the current payment methodology.

Most importantly, drug importation legislation presents potential patient safety issues. Allowing the importation of prescription drugs raises a challenge to ensure that quality assurance standards have been maintained. Prudent importation legislation must ensure

maintenance of quality assurance standards throughout the international drug distribution system. In order to guarantee patient safety, agencies such as the Food and Drug Administration and the United States Customs Service must have the technological and financial resources to address these safety concerns.

Opening the medication distribution channels to medications imported from other counters will open up those channels to counterfeit medications. I am sure all of us are aware of the potential for drug counterfeiting. Drug counterfeiting is a world-wide problem. No country is immune from the threat. However, drug importation, especially personal importation only opens this door wider. Counterfeiters go where the money is and the U.S. market is an excellent target for pharmaceutical fraud, deception and counterfeiting. I commend the FDA for their fight against drug counterfeiting and endorse the FDA report on Combating Counterfeit Drugs released in February. What is of concern is that the report puts forth an excellent strategy for combating drug fraud and assuring drug integrity for Americans, but at the same time, government agencies continue to allow U.S. residents to import substandard, inferior and sometimes counterfeit drug products. We have been fortunate that more people haven't been hurt or died from these products. I have said and continue to say it is only a matter of time before some horrific tragedy involving imported pharmaceuticals occurs.

AMCP believes that until more conclusive data are available as to the likely impact of importation on the cost of drugs and the risks posed to the American citizens, we will oppose proposals that allow the importation of prescription drugs for sale in the United States.

Thank you again for this opportunity and I look forward to answering any questions that you may have.

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[1] Associated Press, "U.K. Pharmacy Filling U.S. Prescriptions," *New York Times*, May 2, 2004.
[2] "Mexican Drugs Shipped to US via Canada, say Consumers," *Scrip: World Pharmaceutical News*, No 2942, April 9, 2004, p 17.